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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,408	03/12/2001	Mathew F. Ogle	1416.20US01	1108

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/804,408

Applicant(s)

OGLE ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-28 and 34-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-28 and 34-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for
5 continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/14/05 has been entered.

The submission presented arguments and did not amend the claims.
10 Claims examined on the merits are 1-9, 11-28 and 34-43, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

15 Claims 1-9, 11-28 and 34-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle et al (5,958,669) in view of Yang et al (5,935,168) for reasons in the previous office actions of 9/8/04 and 1/31/05, and for reasons herein.

The claims are drawn to tissue containing linkers bonded to
20 tissue and bridge molecules bonded between two or more of the linkers, to a method of crosslinking tissue to prepare the tissue having linkers and bridge molecules, to tissue containing modified sites having bridge molecules bonded to two or more of the modified sites, and to a method of crosslinking tissue to prepare the tissue having
25 modified sites and bridge molecules. In all these embodiments,

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functional groups of the bridges are required to be generally non-reactive with other bridges.

Ogle et al disclose crosslinking tissue to fix tissue by reacting the tissue with glutaraldehyde.

5 Yang et al disclose crosslinking tissue with glutaraldehyde, and then reacting with a diamine followed by reacting with additional glutaraldehyde (col 1, line 43 and claims 8-10).

After reacting with glutaraldehyde as disclosed by Ogle et al, it would have been obvious to react with a diamine and then with
10 additional glutaraldehyde as suggested by Yang et al. This will result in the diamine being a linker and the glutaraldehyde being bridge. Additionally, after initially crosslinking with glutaraldehyde some free aldehyde groups will remain that will react with the diamine and result in the glutaraldehyde being a linker and
15 the diamine being a bridge. The aldehyde groups of glutaraldehyde are generally non-reactive with other aldehyde groups of another glutaraldehyde under certain conditions disclosed by Ogle et al that control self-polymerizing. The amine groups of a diamine will not react with amine groups of another diamine. This will result in a
20 bridge not reacting with another bridge.

Response to Arguments

Applicant's arguments filed 3/14/05 have been fully considered but they are not persuasive.

Applicants urge that glutaraldehyde cannot be a bridge since
25 aldehyde groups of glutaraldehyde will not only react with diamines,

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but also will react with any other primary nitrogens in tissue, and glutaraldehyde self-polymerizes as the article by Kiernan indicates.

However, the present claims do not exclude groups of the bridges being reactive with primary nitrogens of tissue. The claims require
5 the bridges to be generally non-reactive with other bridges, and do not require non-reactively with tissue. Even if the claims required groups of the bridges to be generally non-reactive with unmodified tissue as disclosed in the specification (page 6, lines 11-13), the term "generally non-reactive" will not exclude some reaction of bridge
10 groups with tissue.

As to glutaraldehyde self-polymerizing, Ogle et al disclose how this can be controlled (col 4, lines 1-9, col 6, lines 24-30 and col 7, lines 34-39). Reciting "generally non-reactive" in the claims does not exclude the bridge undergoing a small amount of self-
15 polymerization that occurs in Ogle et al when reducing the quantity of large oligomers and obtaining a high quantity of monomers.

Furthermore, as set forth above, when reacting glutaraldehyde with tissue as disclosed by Olge et al and then reacting with a diamine as suggested by Yang et al, the diamine can be the bridge and
20 glutaraldehyde the linker. Some free aldehyde groups will remain after reacting tissue with gluraraldehydye as indicated by Ogle et al disclosing determining unreacted aldehyde functional groups (col 6, lines 52-54). When the diamine is added, amine groups of the diamine will inherently react with unreacted aldehyde groups and form a bridge
25 between the groups.

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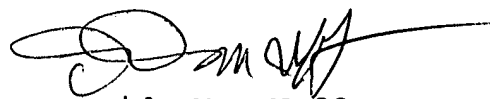
While the present specification does not mention gluraraldehyde as a bridge and discloses glutaraldehyde as a linker, there is no disclosure that glutaraldehyde cannot be a bridge.

Conclusion

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

10 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

15 Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private
20 PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
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